IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Bardy	
Application No.: Unassigned	Group Art Unit: Unassigned
Filed: August 22, 2003	
Title: System And Method For Diagnosing And Monitoring Outcomes Of Atrial Fribrillation For Automated Remote Patient Care	Examiner: Unassigned
Attorney Docket No.: 020.0342.US.CON	

Assistant Commissioner for Patents
Alexandria, VA 22313-1450

DRAWING TRANSMITTAL LETTER

Sir:

Enclosed herewith please find:

( )____ sheets of redlined drawing(s) which indicate proposed changes to the drawing(s). Upon approval of these proposed changes, formal drawing(s) will be submitted.

( )____ sheets of corrected formal drawing(s), as required by the Notice of Patent Drawings Objection (PTO-948) which accompanied the Office Action dated _____.

( )____ sheets of corrected formal drawing(s), as required by the Notice of Patent Drawing(s) Objection (PTO-948) and approved in the Notice of Allowability dated _____.

(X) 33 sheets of formal drawings, submitted with the enclosed continuation Utility Patent Application.

Examiner's approval of the entry of these drawings is respectfully requested.

Respectfully Submitted,

By_____
Patrick J.S. Inouye, Esq.

Attorney/Agent for Applicant(s)
Reg. No. 40297

Date: August 22, 2003

Telephone No.: (206) 381-3900

Figure 1.

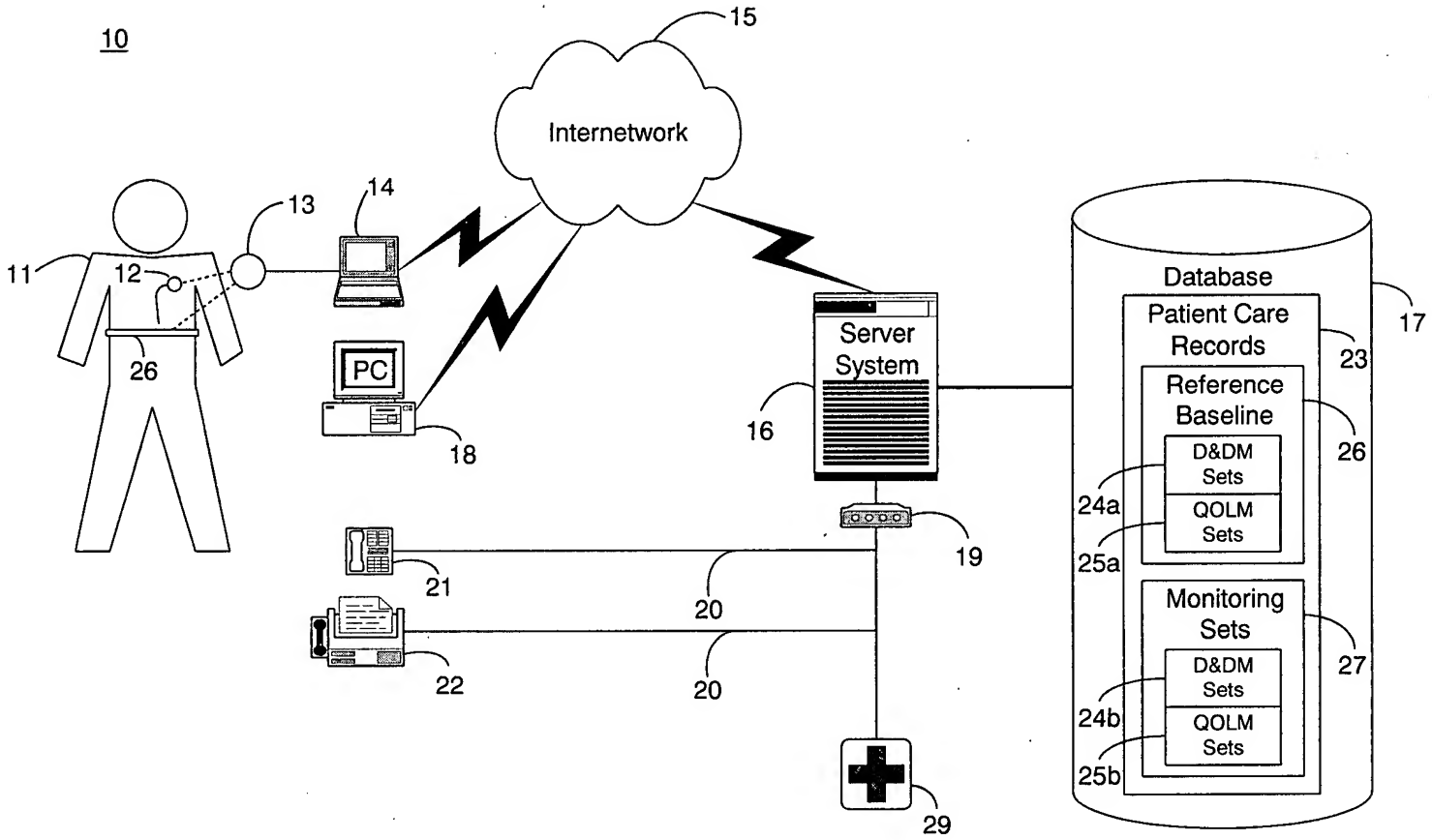

10
15
Internetwork
11
12
13
14
26
PC
18
16
Server System
19
21
20
22
20
29
Database
17
Patient Care Records
23
Reference Baseline
26
D&DM Sets
QOLM Sets
24a
25a
Monitoring Sets
27
D&DM Sets
QOLM Sets
24b
25b

Figure 2.

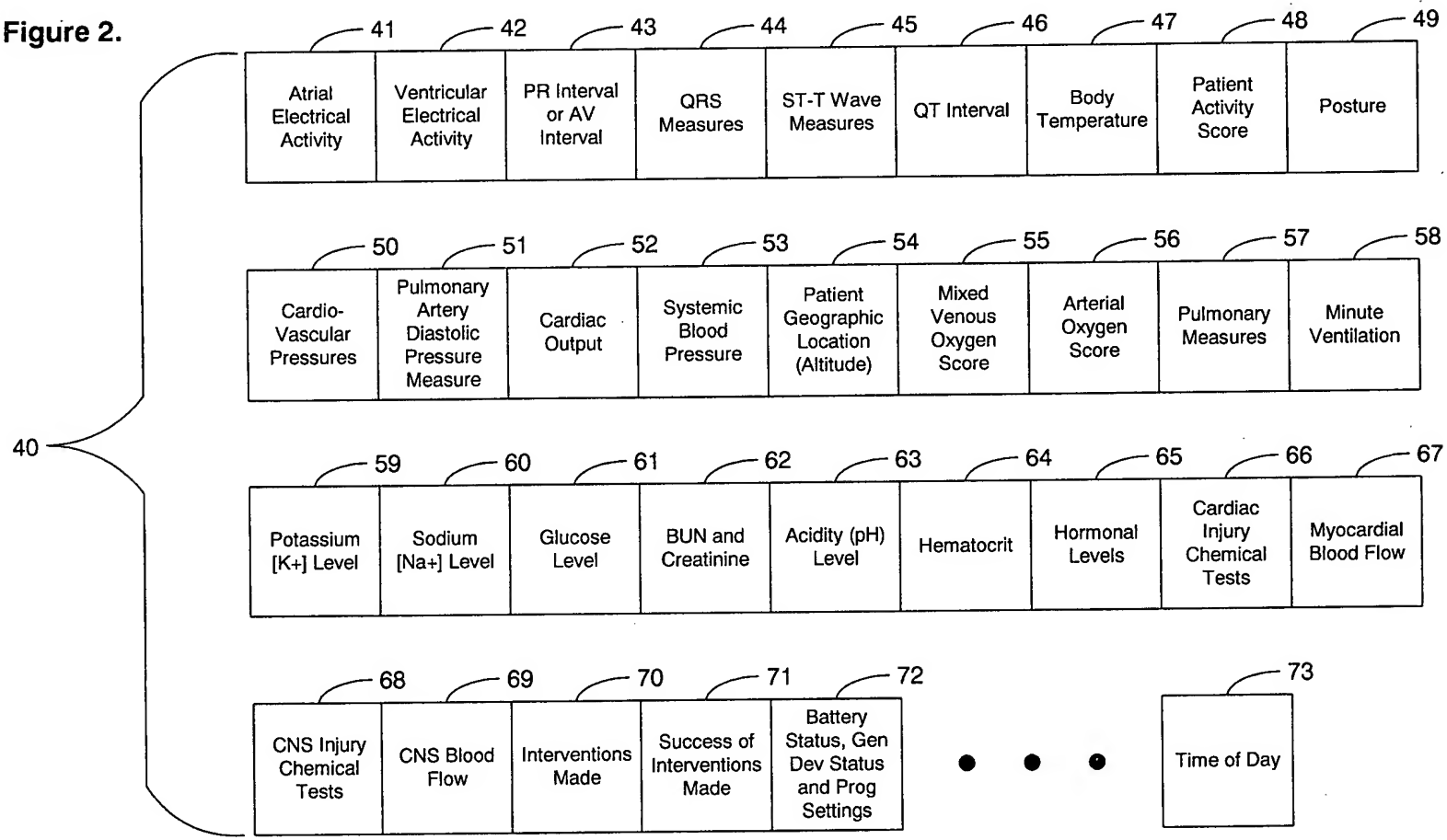

40
41
Atrial Electrical Activity
42
Ventricular Electrical Activity
43
PR Interval or AV Interval
44
QRS Measures
45
ST-T Wave Measures
46
QT Interval
47
Body Temperature
48
Patient Activity Score
49
Posture
50
Cardio-Vascular Pressures
51
Pulmonary Artery Diastolic Pressure Measure
52
Cardiac Output
53
Systemic Blood Pressure
54
Patient Geographic Location (Altitude)
55
Mixed Venous Oxygen Score
56
Arterial Oxygen Score
57
Pulmonary Measures
58
Minute Ventilation
59
Potassium [K+] Level
60
Sodium [Na+] Level
61
Glucose Level
62
BUN and Creatinine
63
Acidity (pH) Level
64
Hematocrit
65
Hormonal Levels
66
Cardiac Injury Chemical Tests
67
Myocardial Blood Flow
68
CNS Injury Chemical Tests
69
CNS Blood Flow
70
Interventions Made
71
Success of Interventions Made
72
Battery Status, Gen Dev Status and Prog Settings
73
Time of Day

Figure 3.

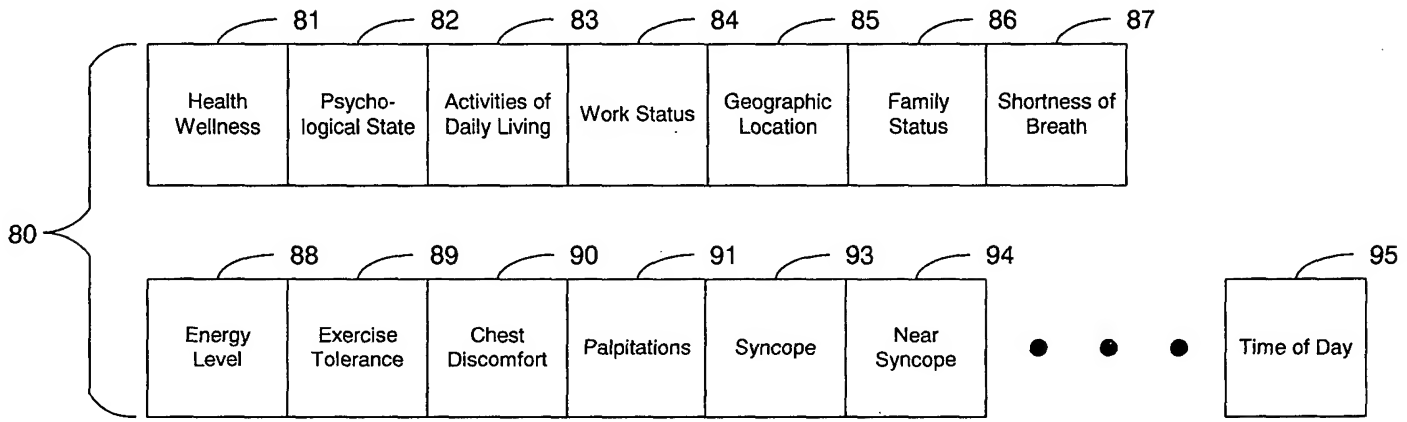

80
81
Health Wellness
82
Psycho-logical State
83
Activities of Daily Living
84
Work Status
85
Geographic Location
86
Family Status
87
Shortness of Breath
88
Energy Level
89
Exercise Tolerance
90
Chest Discomfort
91
Palpitations
93
Syncope
94
Near Syncope
95
Time of Day

Figure 4.

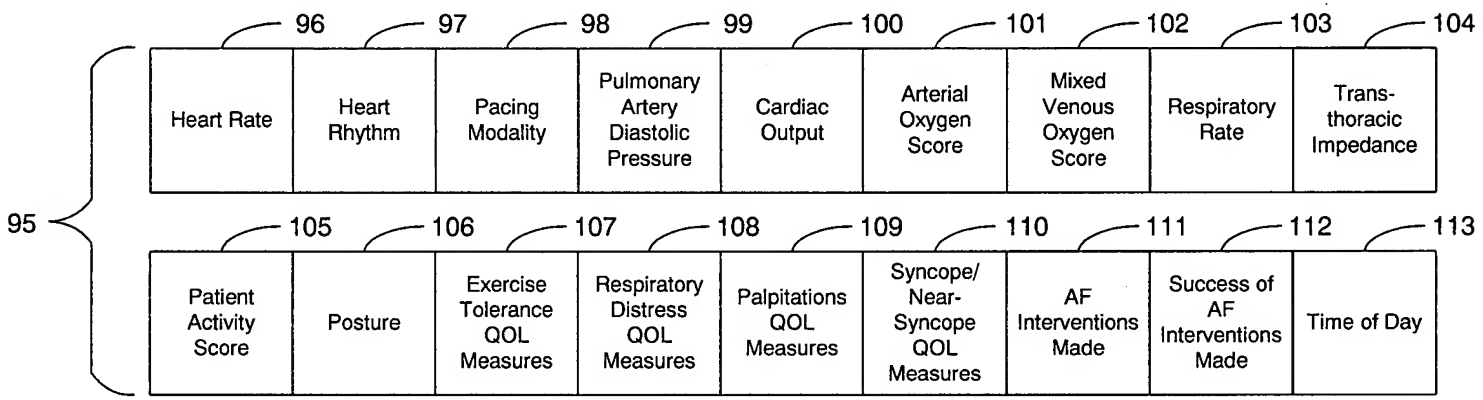

95
96
Heart Rate
97
Heart Rhythm
98
Pacing Modality
99
Pulmonary Artery Diastolic Pressure
100
Cardiac Output
101
Arterial Oxygen Score
102
Mixed Venous Oxygen Score
103
Respiratory Rate
104
Trans-thoracic Impedance
105
Patient Activity Score
106
Posture
107
Exercise Tolerance QOL Measures
108
Respiratory Distress QOL Measures
109
Palpitations QOL Measures
110
Syncope/ Near-Syncope QOL Measures
111
AF Interventions Made
112
Success of AF Interventions Made
113
Time of Day

Figure 5.

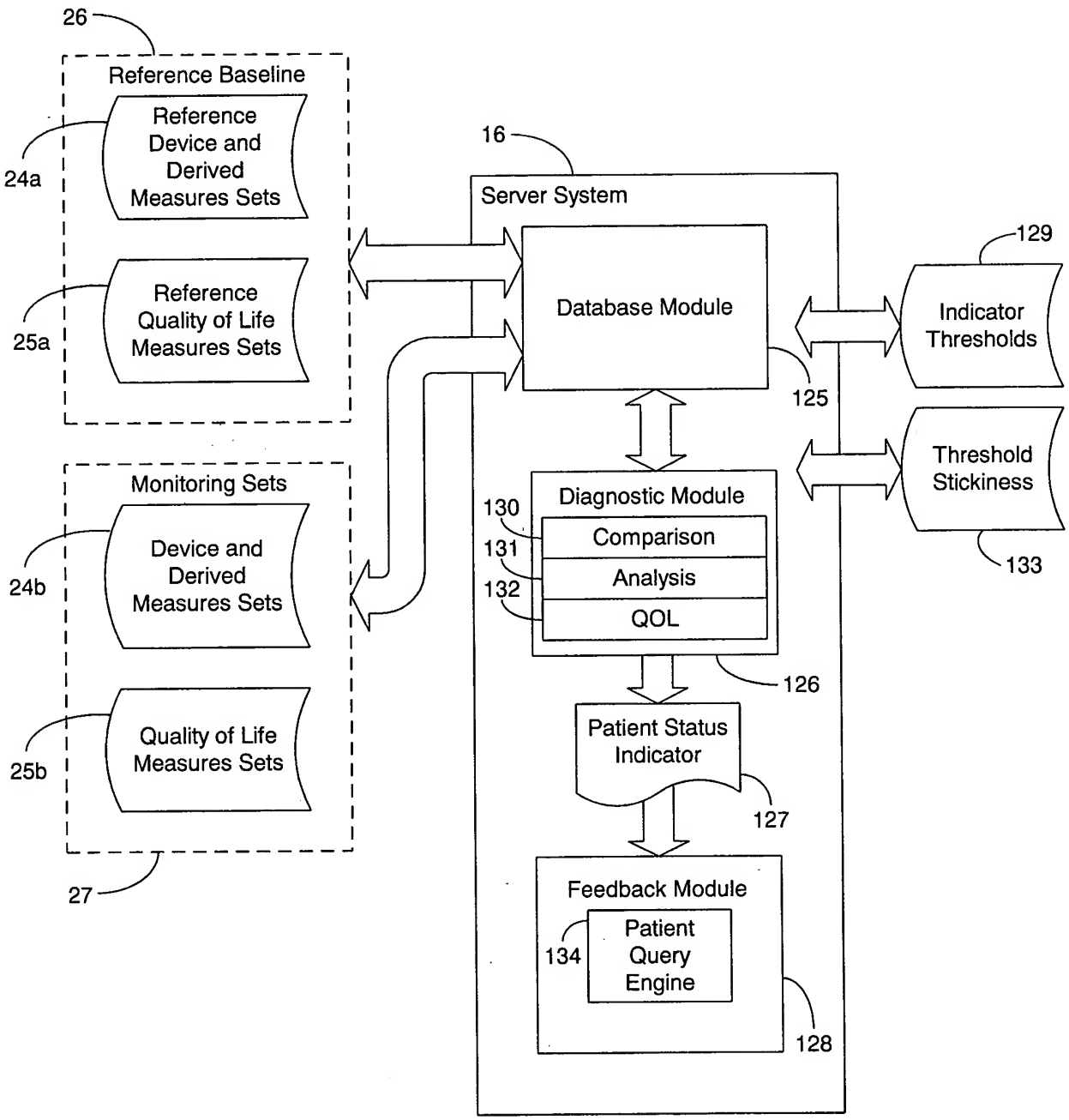

26
Reference Baseline
Reference Device and Derived Measures Sets
24a
Reference Quality of Life Measures Sets
25a
Monitoring Sets
Device and Derived Measures Sets
24b
Quality of Life Measures Sets
25b
27
16
Server System
Database Module
129
Indicator Thresholds
125
Threshold Stickiness
133
Diagnostic Module
130
Comparison
131
Analysis
132
QOL
126
Patient Status Indicator
127
Feedback Module
134
Patient Query Engine
128

Figure 6.

Patient 1

Set 0				Set n-2	Set n-1	Set n
X_0	•	•	•	X_{n-2}	X_{n-1}	X_n
Y_0	•	•	•	Y_{n-2}	Y_{n-1}	Y_n
Z_0	•	•	•	Z_{n-2}	Z_{n-1}	Z_n

time →

Patient 2

Set 0				Set n-2	Set n-1	Set n
$X_{0'}$	•	•	•	$X_{n-2'}$	$X_{n-1'}$	$X_{n'}$
$Y_{0'}$	•	•	•	$Y_{n-2'}$	$Y_{n-1'}$	$Y_{n'}$
$Z_{0'}$	•	•	•	$Z_{n-2'}$	$Z_{n-1'}$	$Z_{n'}$

time →

Patient 3

Set 0				Set n-2	Set n-1	Set n
$X_{0''}$	•	•	•	$X_{n-2''}$	$X_{n-1''}$	$X_{n''}$
$Y_{0''}$	•	•	•	$Y_{n-2''}$	$Y_{n-1''}$	$Y_{n''}$
$Z_{0''}$	•	•	•	$Z_{n-2''}$	$Z_{n-1''}$	$Z_{n''}$

time →

Figure 7.

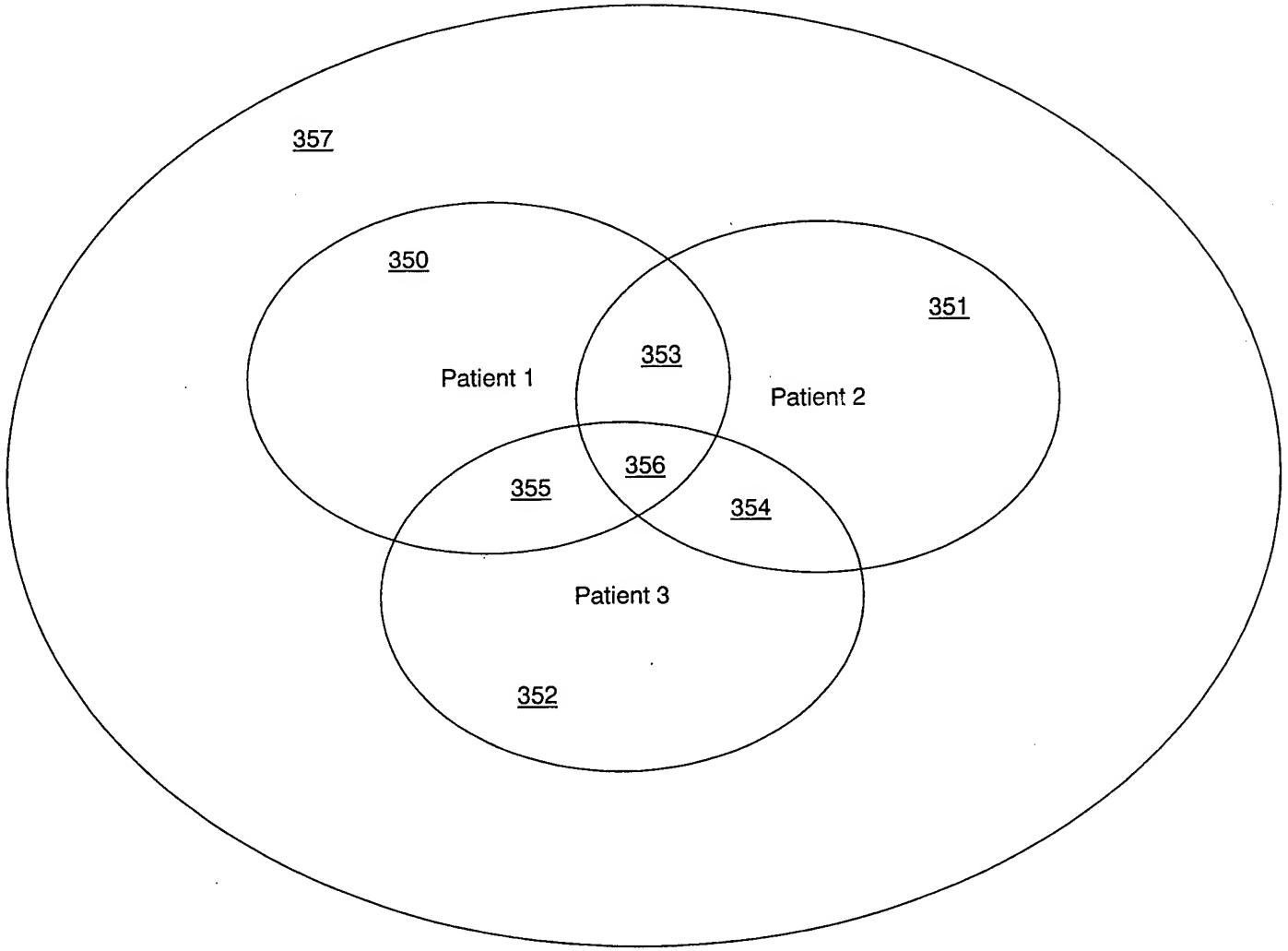


Figure 8A.

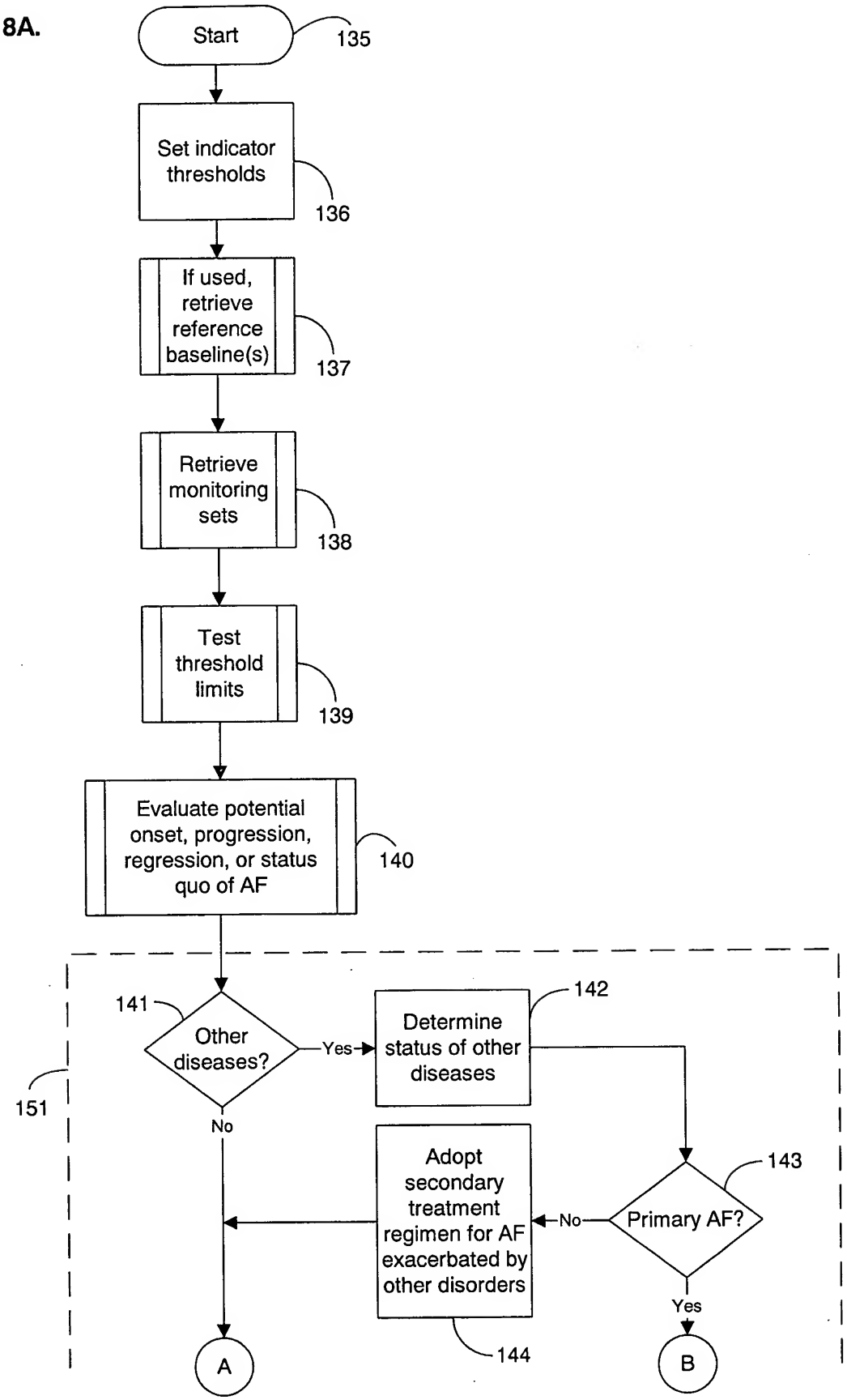

Start
135
Set indicator thresholds
136
If used, retrieve reference baseline(s)
137
Retrieve monitoring sets
138
Test threshold limits
139
Evaluate potential onset, progression, regression, or status quo of AF
140
151
141
Other diseases?
Yes
No
142
Determine status of other diseases
Adopt secondary treatment regimen for AF exacerbated by other disorders
144
143
Primary AF?
No
Yes
A
B

Figure 8B.

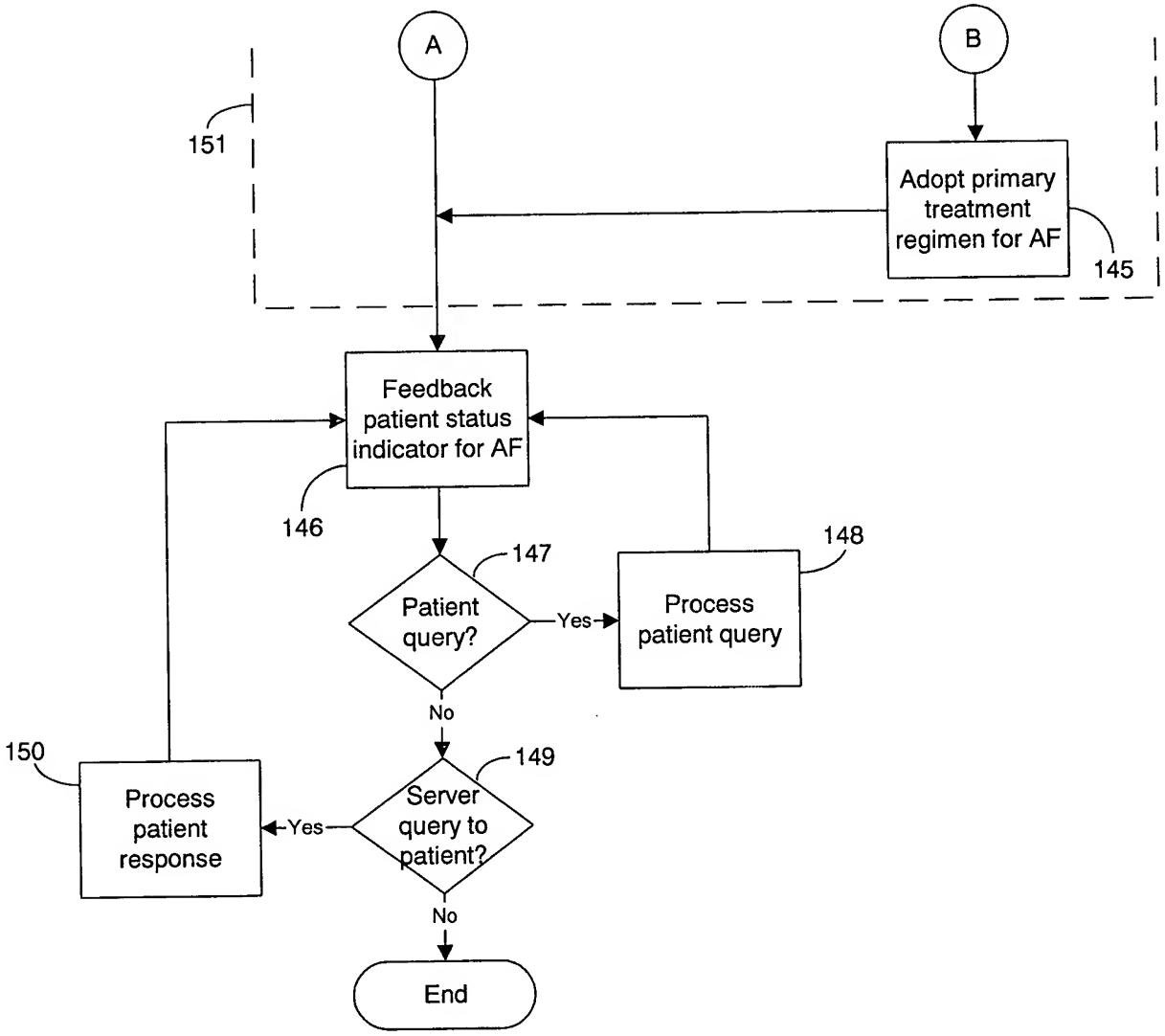

A
B
151
Adopt primary treatment regimen for AF
145
Feedback patient status indicator for AF
146
147
148
Patient query?
Yes
Process patient query
No
150
149
Process patient response
Yes
Server query to patient?
No
End

Figure 9.

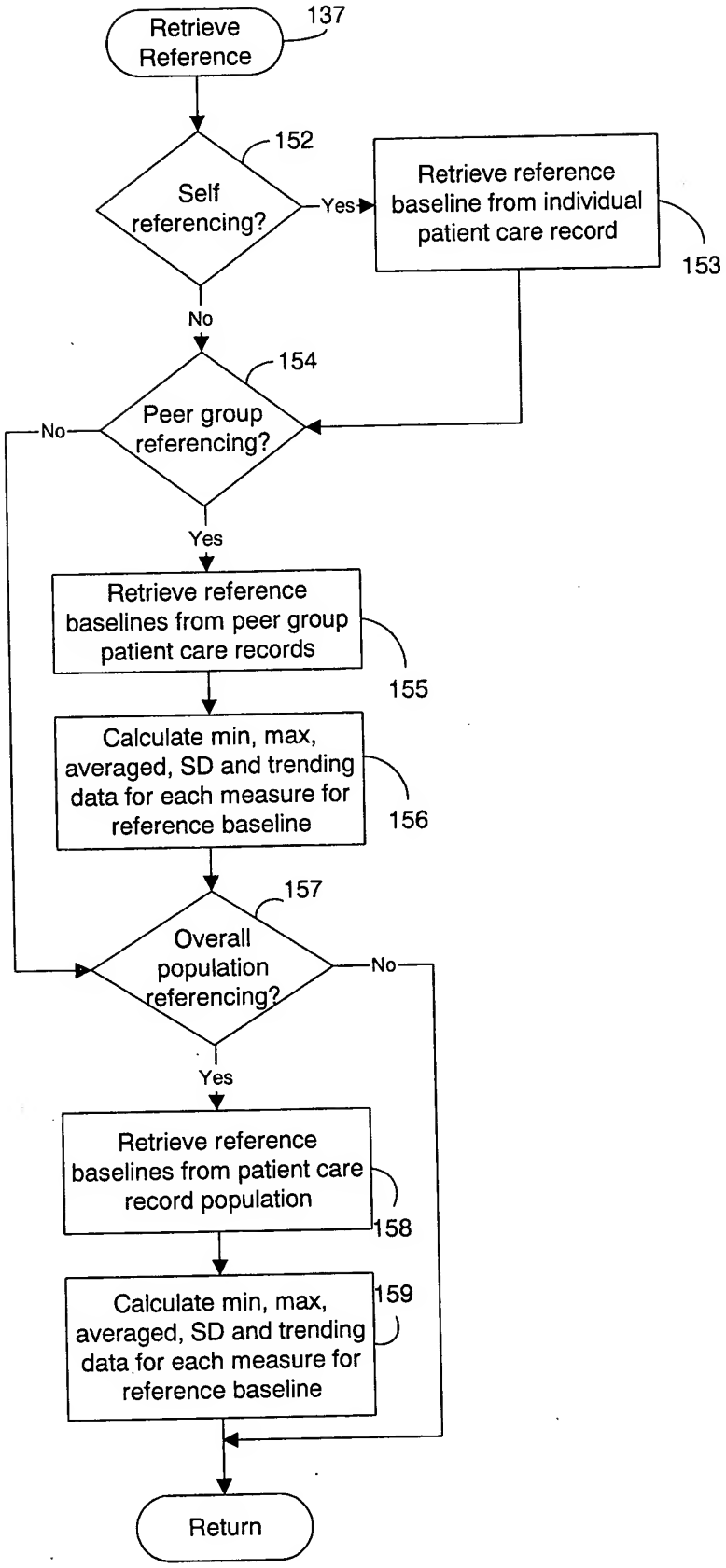

Retrieve Reference
137
Self referencing?
152
Yes
Retrieve reference baseline from individual patient care record
153
No
Peer group referencing?
154
No
Yes
Retrieve reference baselines from peer group patient care records
155
Calculate min, max, averaged, SD and trending data for each measure for reference baseline
156
Overall population referencing?
157
No
Yes
Retrieve reference baselines from patient care record population
158
Calculate min, max, averaged, SD and trending data for each measure for reference baseline
159
Return

Figure 10.

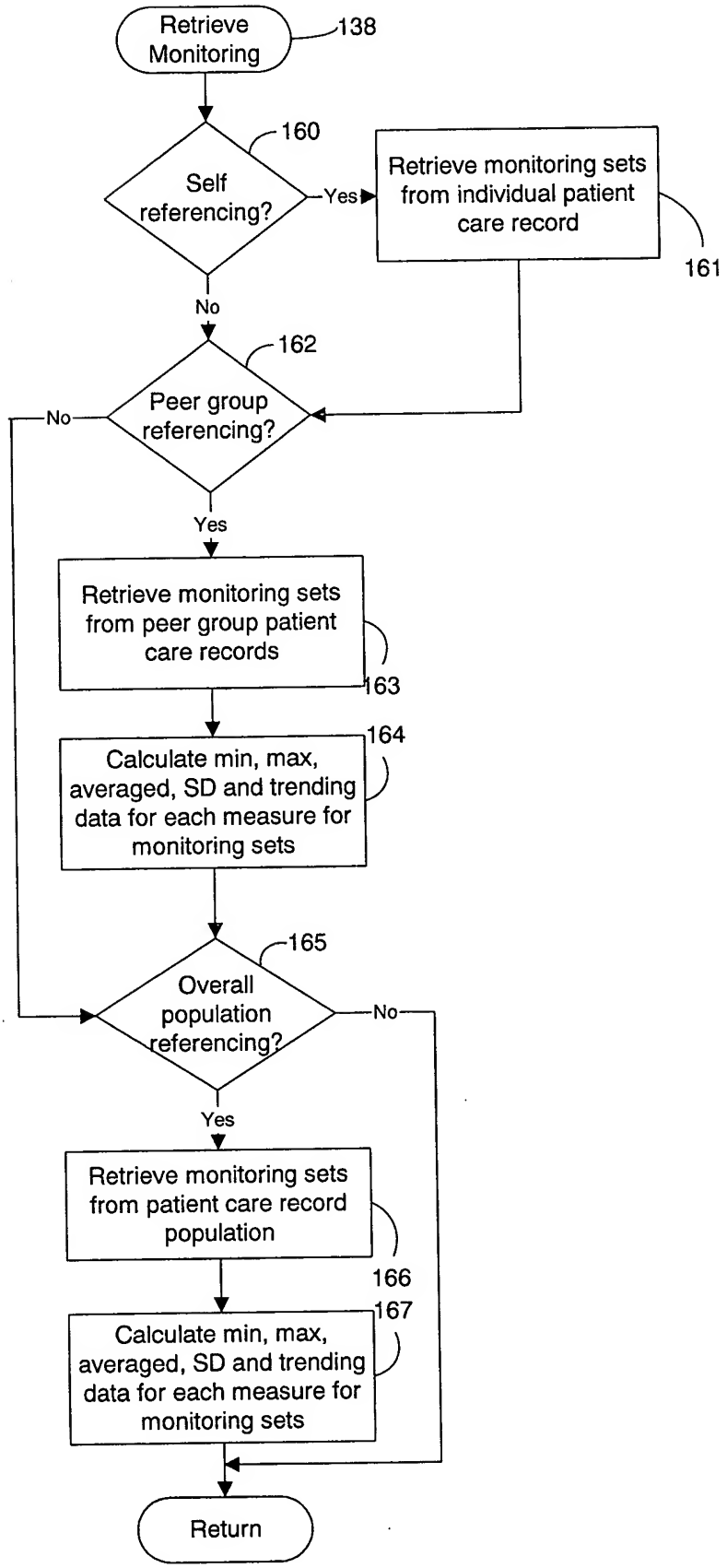

Retrieve Monitoring
138
160
Self referencing?
Yes
Retrieve monitoring sets from individual patient care record
161
No
162
Peer group referencing?
No
Yes
Retrieve monitoring sets from peer group patient care records
163
164
Calculate min, max, averaged, SD and trending data for each measure for monitoring sets
165
Overall population referencing?
No
Yes
Retrieve monitoring sets from patient care record population
166
167
Calculate min, max, averaged, SD and trending data for each measure for monitoring sets
Return

Figure 11A.

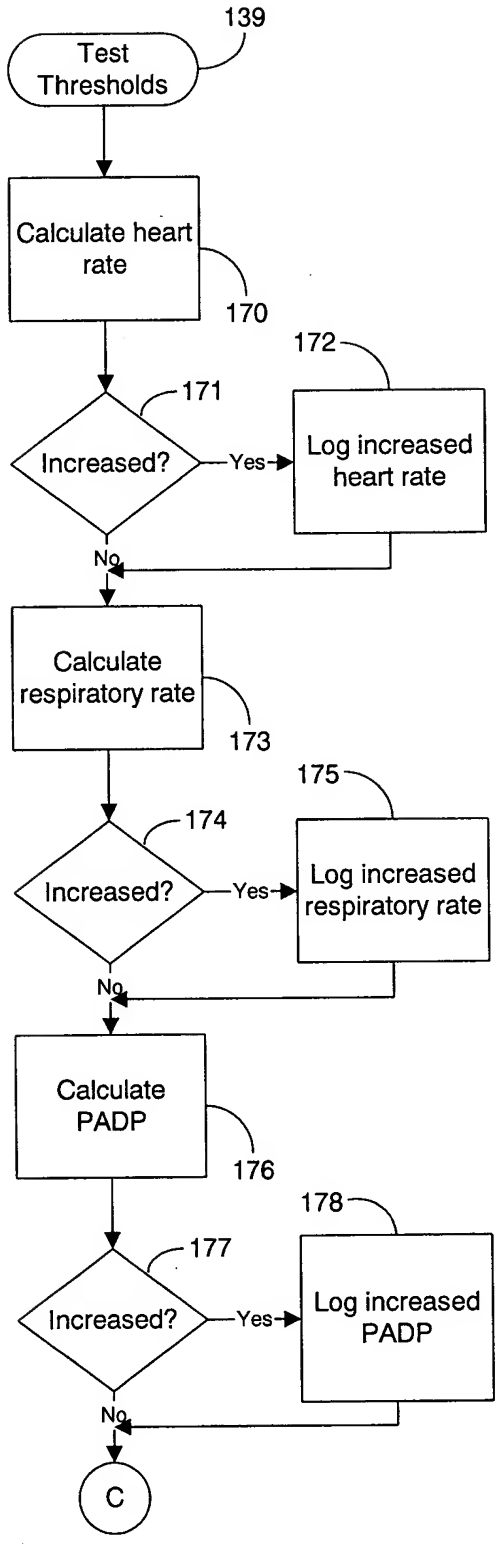

139
Test Thresholds
Calculate heart rate
170
172
171
Increased?
Yes
Log increased heart rate
No
Calculate respiratory rate
173
175
174
Increased?
Yes
Log increased respiratory rate
No
Calculate PADP
176
178
177
Increased?
Yes
Log increased PADP
No
C

Figure 11B.

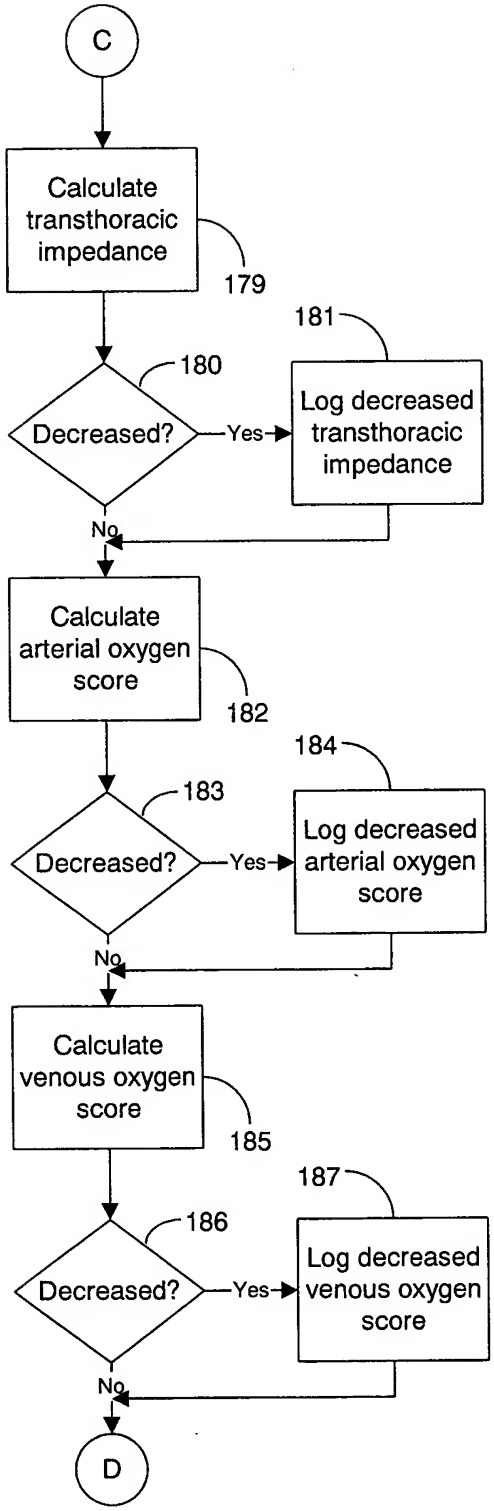

C
Calculate transthoracic impedance
179
181
180
Decreased?
Yes
Log decreased transthoracic impedance
No
Calculate arterial oxygen score
182
184
183
Decreased?
Yes
Log decreased arterial oxygen score
No
Calculate venous oxygen score
185
187
186
Decreased?
Yes
Log decreased venous oxygen score
No
D

Figure 11C.

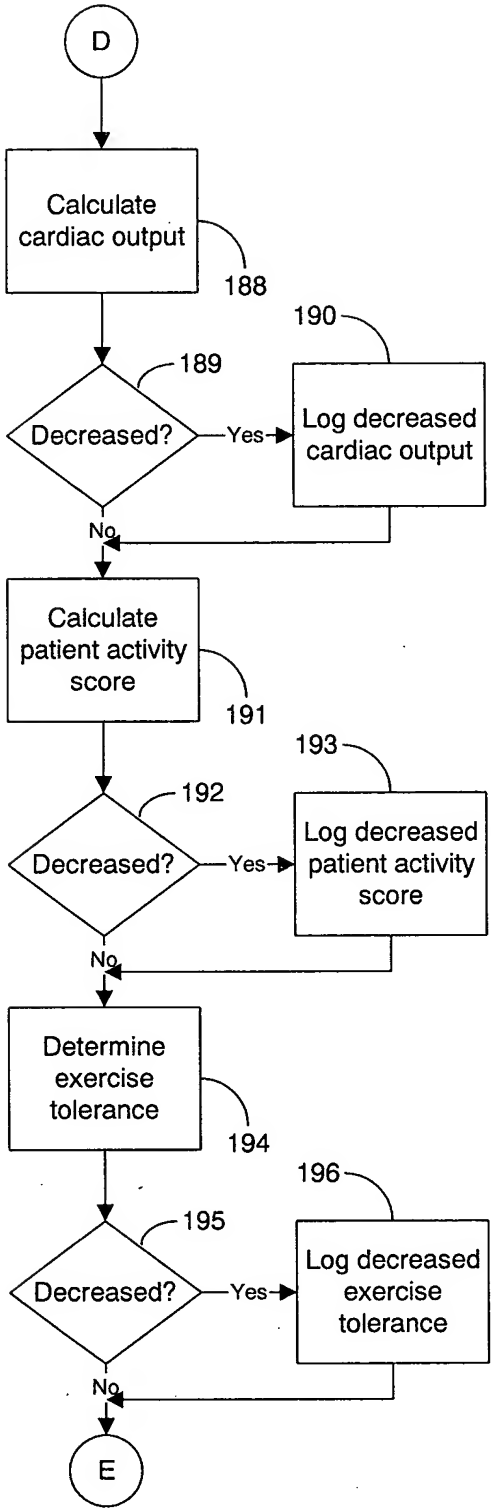

D
Calculate cardiac output
188
190
189
Decreased?
Yes
Log decreased cardiac output
No
Calculate patient activity score
191
193
192
Decreased?
Yes
Log decreased patient activity score
No
Determine exercise tolerance
194
196
195
Decreased?
Yes
Log decreased exercise tolerance
No
E

Figure 11D.

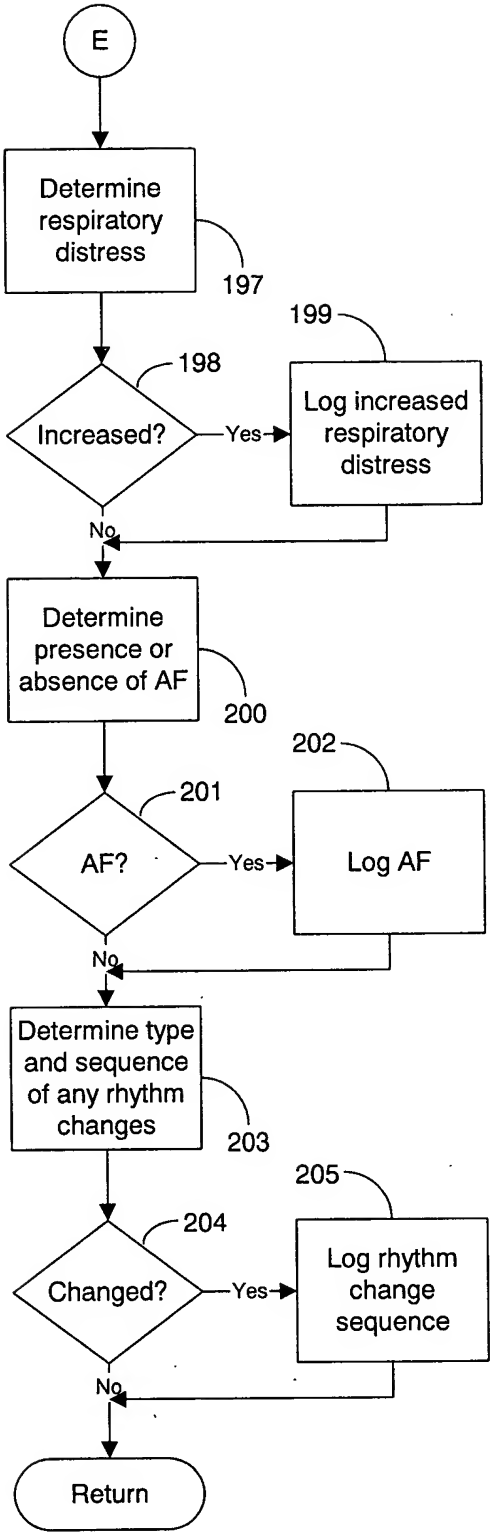

E
Determine respiratory distress
197
199
198
Increased?
Yes
Log increased respiratory distress
No
Determine presence or absence of AF
200
202
201
AF?
Yes
Log AF
No
Determine type and sequence of any rhythm changes
203
205
204
Changed?
Yes
Log rhythm change sequence
No
Return

Figure 12A.

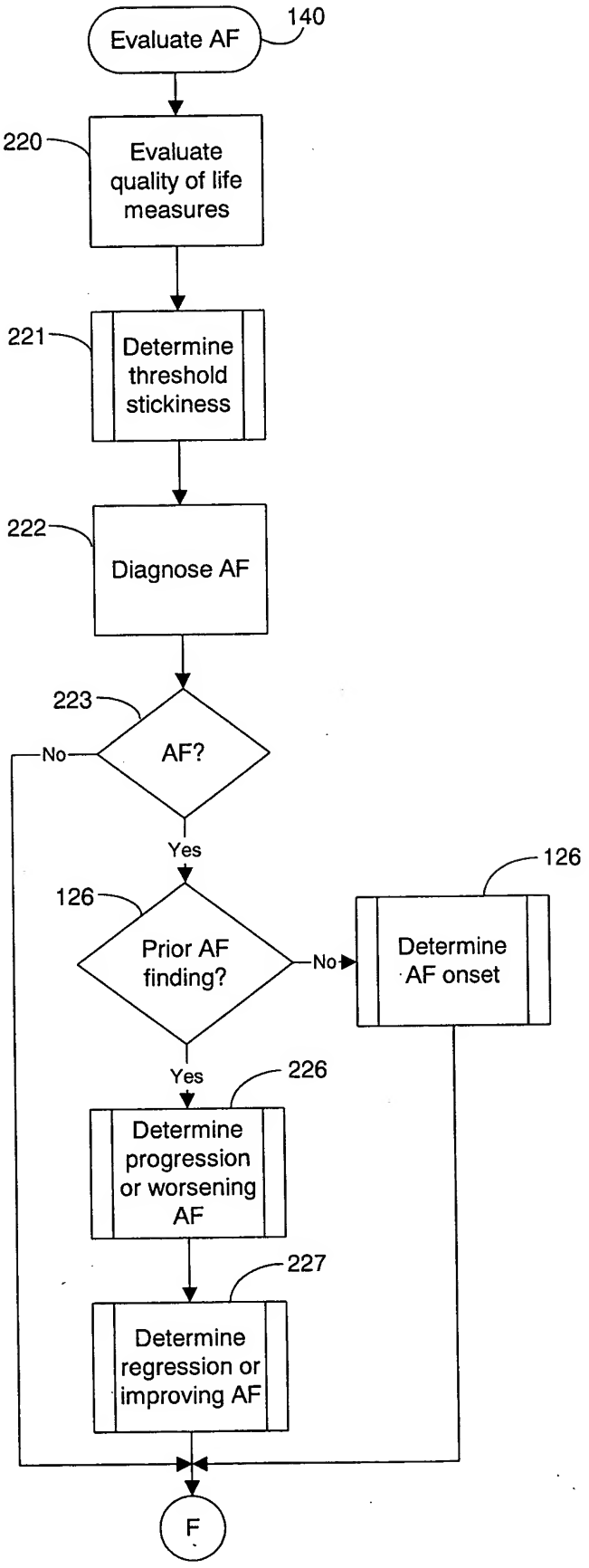

Evaluate AF
140
220
Evaluate quality of life measures
221
Determine threshold stickiness
222
Diagnose AF
223
AF?
No
Yes
126
Prior AF finding?
No
126
Determine AF onset
Yes
226
Determine progression or worsening AF
227
Determine regression or improving AF
F

Figure 12B.

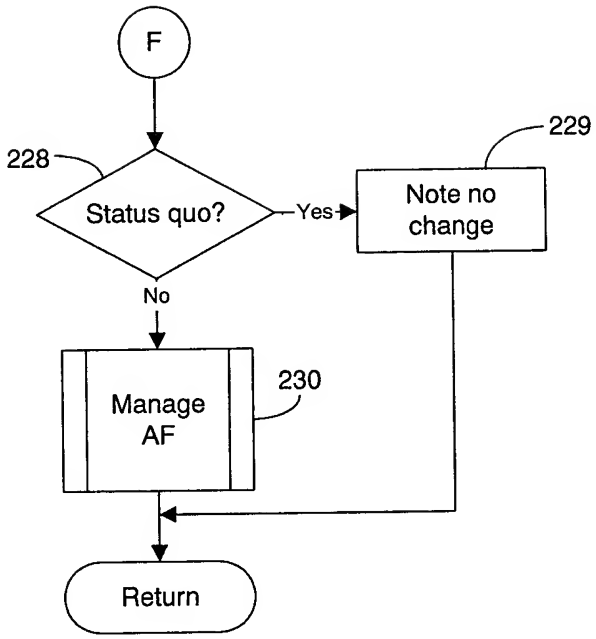

F
228
Status quo?
Yes
229
Note no change
No
230
Manage AF
Return

Figure 13A.

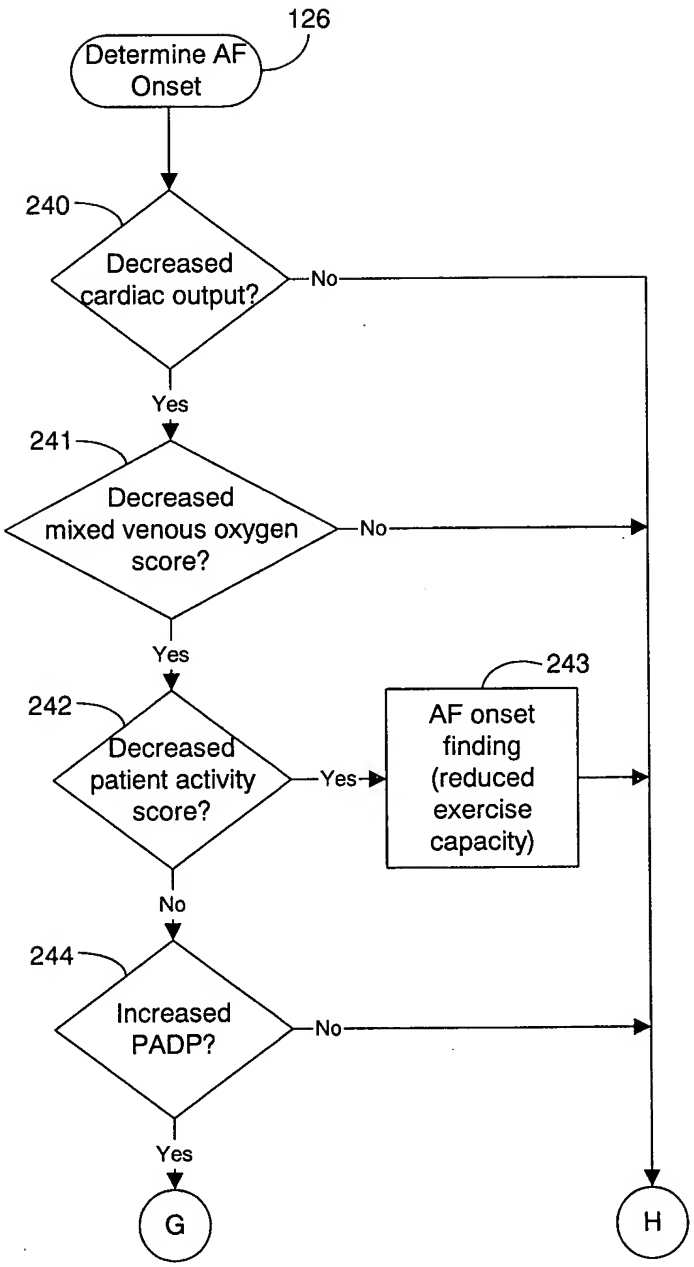

126
Determine AF Onset
240
Decreased cardiac output?
No
Yes
241
Decreased mixed venous oxygen score?
No
Yes
242
Decreased patient activity score?
Yes
243
AF onset finding (reduced exercise capacity)
No
244
Increased PADP?
No
Yes
G
H

Figure 13B.

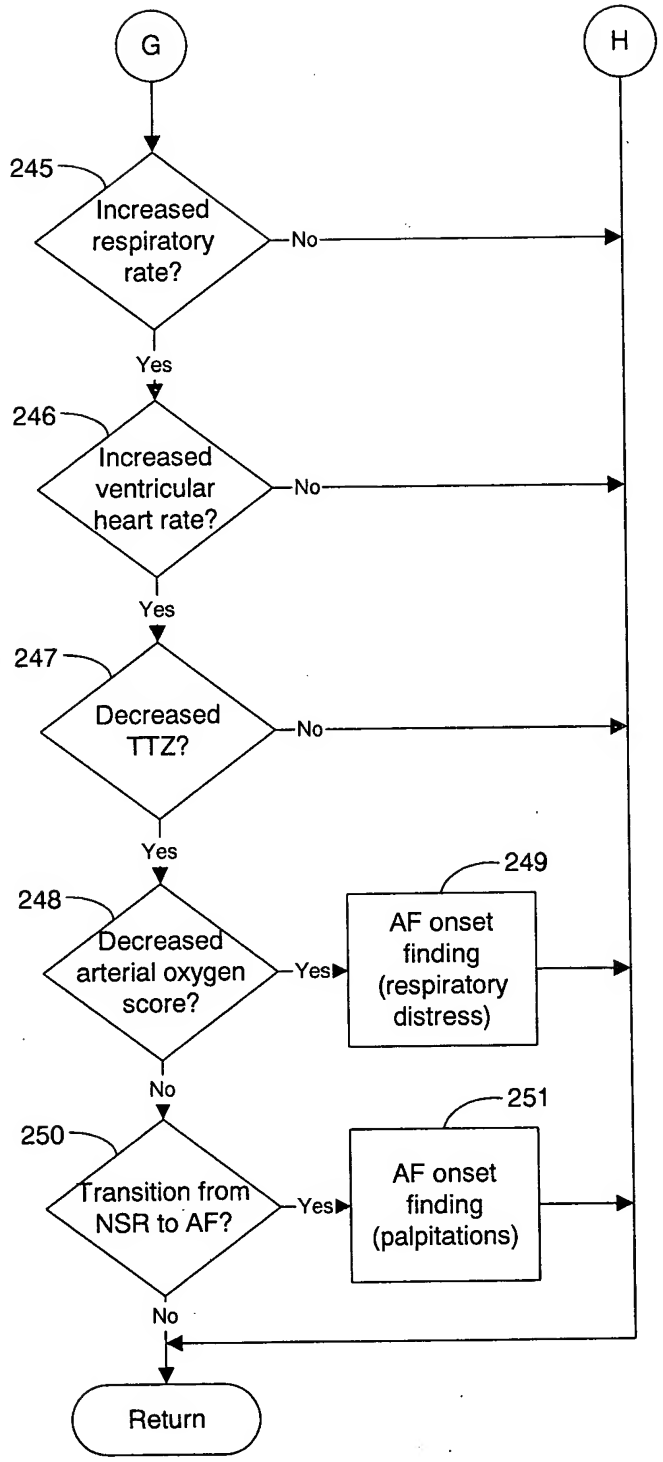

G
H
245
Increased respiratory rate?
No
Yes
246
Increased ventricular heart rate?
No
Yes
247
Decreased TTZ?
No
Yes
248
Decreased arterial oxygen score?
Yes
249
AF onset finding (respiratory distress)
No
250
Transition from NSR to AF?
Yes
251
AF onset finding (palpitations)
No
Return

Figure 14A.

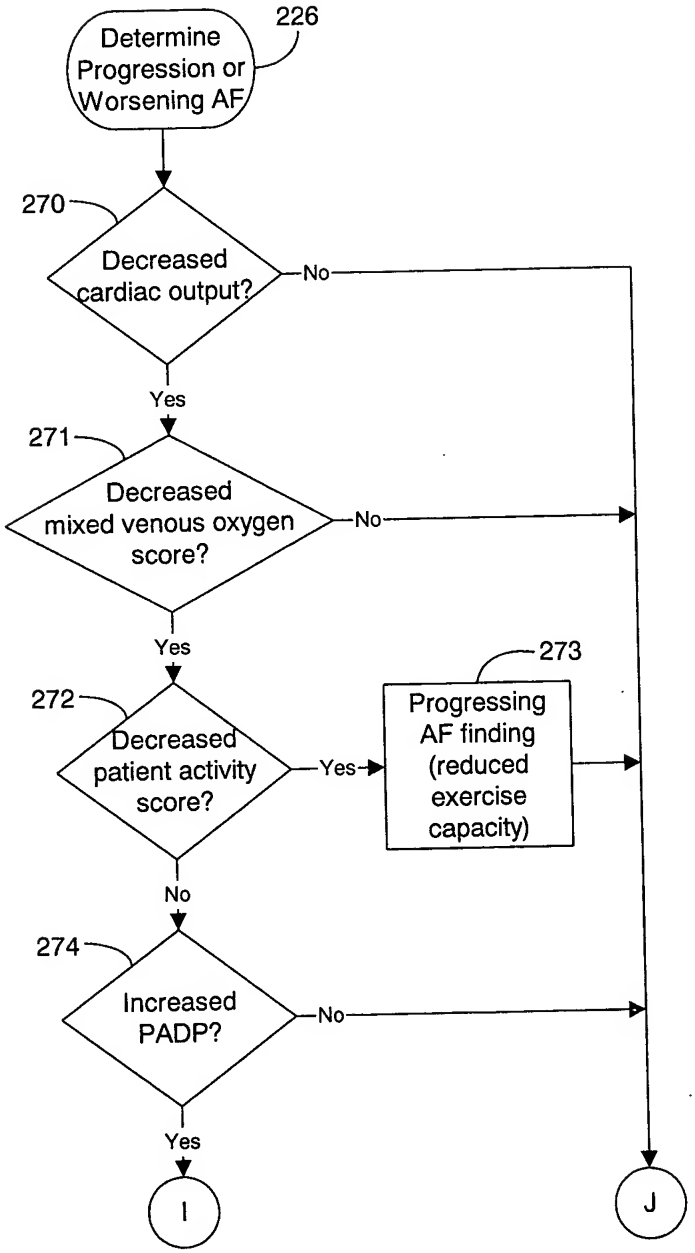

Determine Progression or Worsening AF
226
270
Decreased cardiac output?
No
Yes
271
Decreased mixed venous oxygen score?
No
Yes
272
Decreased patient activity score?
Yes
273
Progressing AF finding (reduced exercise capacity)
No
274
Increased PADP?
No
Yes
I
J

Figure 14B.

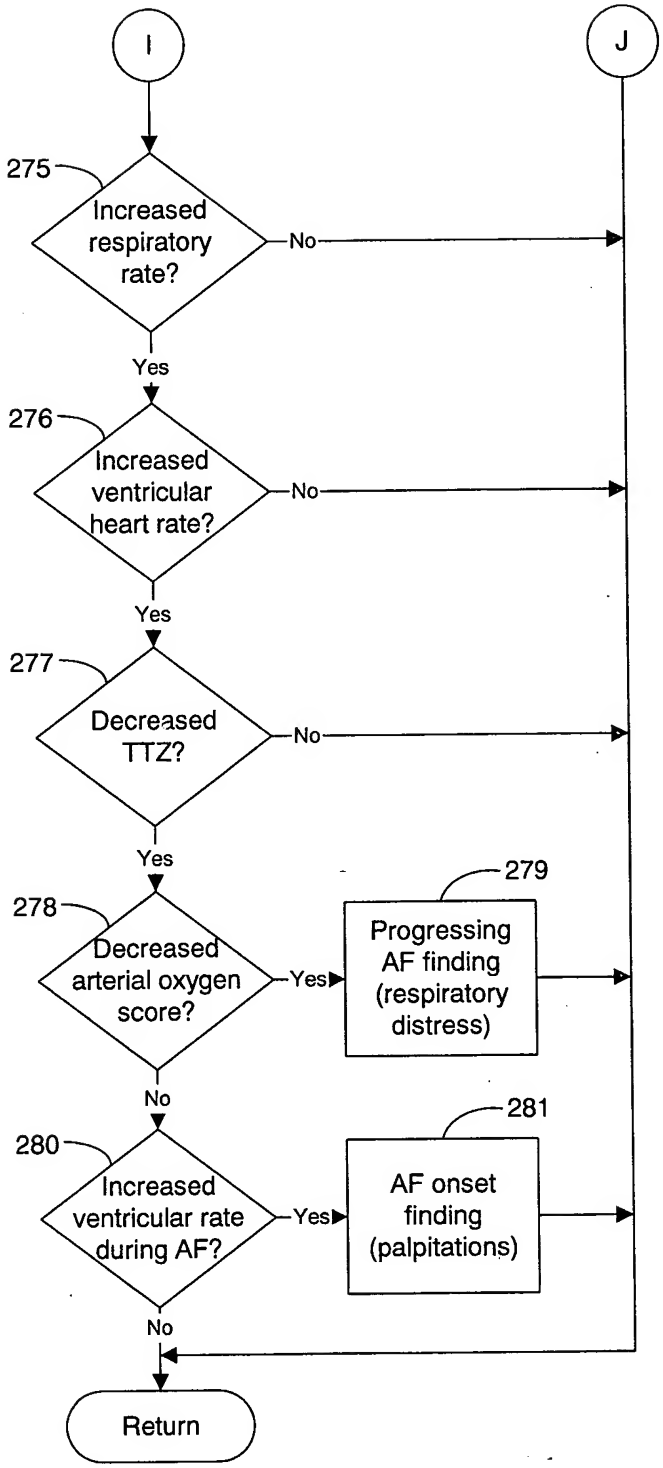

I
J
275
Increased respiratory rate?
No
Yes
276
Increased ventricular heart rate?
No
Yes
277
Decreased TTZ?
No
Yes
278
Decreased arterial oxygen score?
Yes
279
Progressing AF finding (respiratory distress)
No
280
Increased ventricular rate during AF?
Yes
281
AF onset finding (palpitations)
No
Return

Figure 15A.

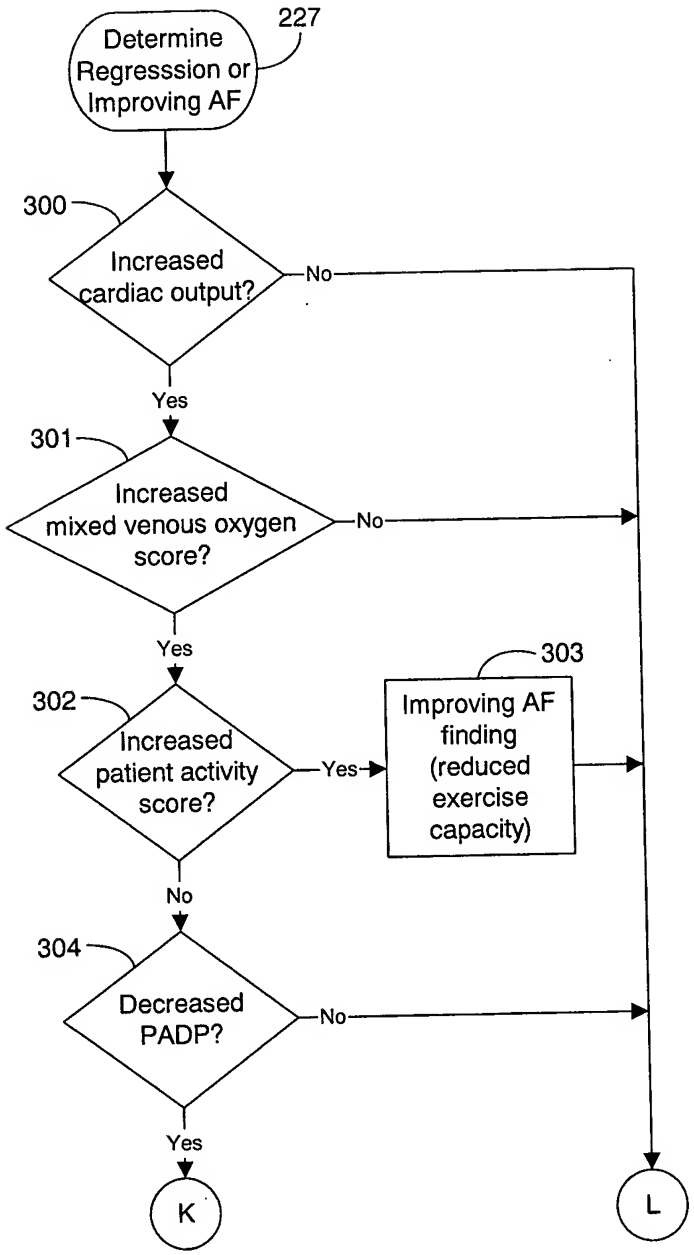

Determine Regresssion or Improving AF
227
300
Increased cardiac output?
No
Yes
301
Increased mixed venous oxygen score?
No
Yes
303
302
Increased patient activity score?
Yes
Improving AF finding (reduced exercise capacity)
No
304
Decreased PADP?
No
Yes
K
L

Figure 15B.

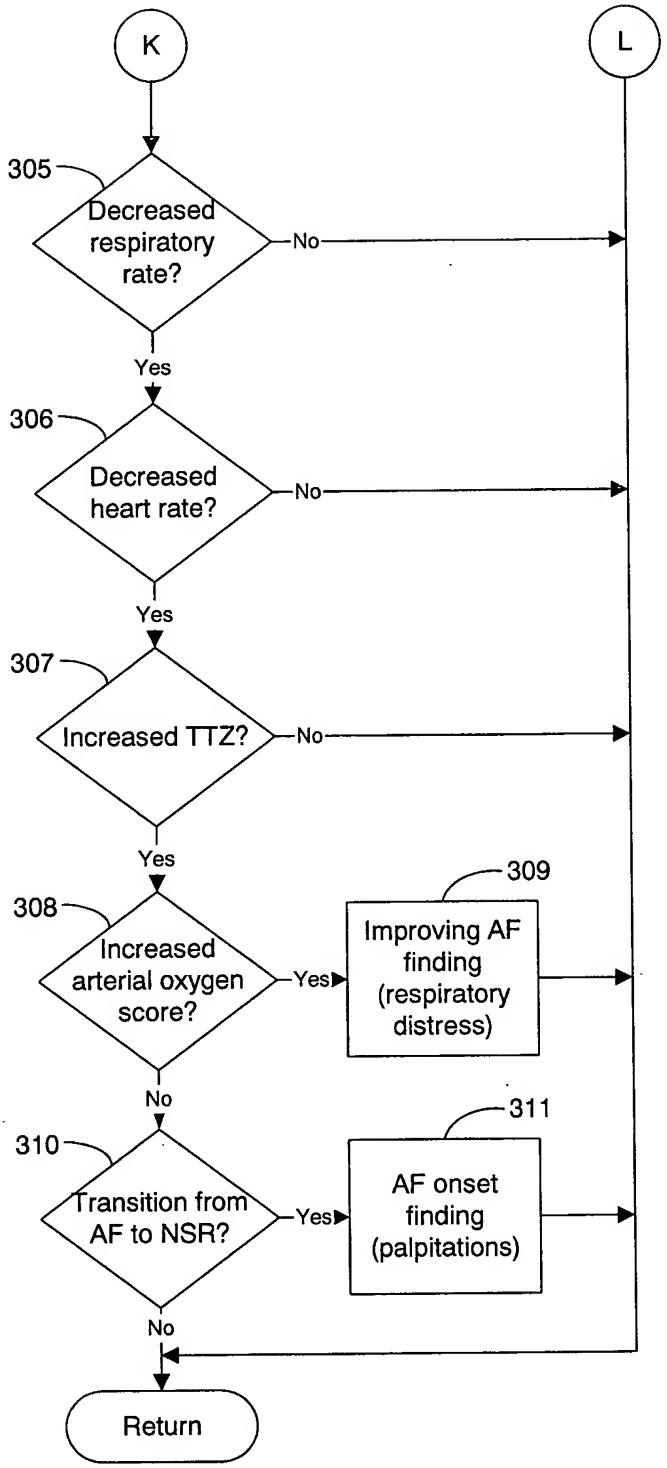

K
L
305
Decreased respiratory rate?
No
Yes
306
Decreased heart rate?
No
Yes
307
Increased TTZ?
No
Yes
308
Increased arterial oxygen score?
Yes
309
Improving AF finding (respiratory distress)
No
310
Transition from AF to NSR?
Yes
311
AF onset finding (palpitations)
No
Return

Figure 16.

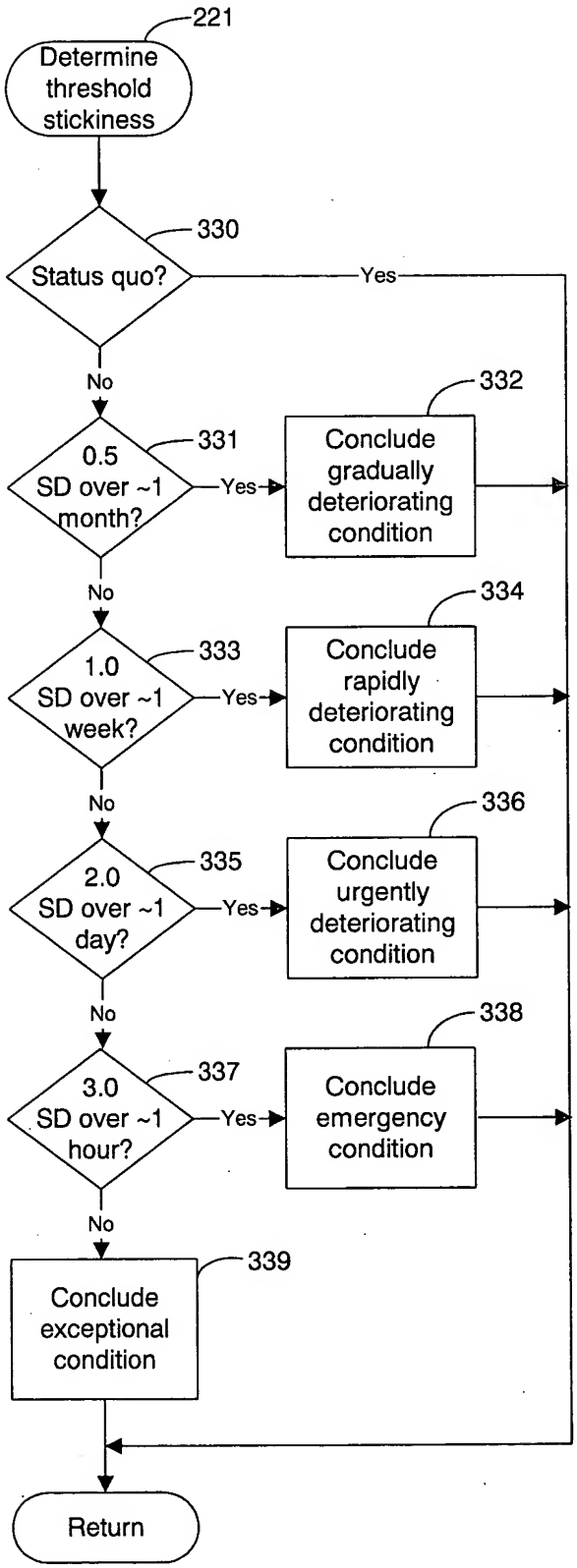

221
Determine threshold stickiness
330
Status quo?
Yes
No
332
0.5 SD over ~1 month?
331
Yes
Conclude gradually deteriorating condition
No
334
1.0 SD over ~1 week?
333
Yes
Conclude rapidly deteriorating condition
No
336
2.0 SD over ~1 day?
335
Yes
Conclude urgently deteriorating condition
No
338
3.0 SD over ~1 hour?
337
Yes
Conclude emergency condition
No
339
Conclude exceptional condition
Return

Figure 17A.

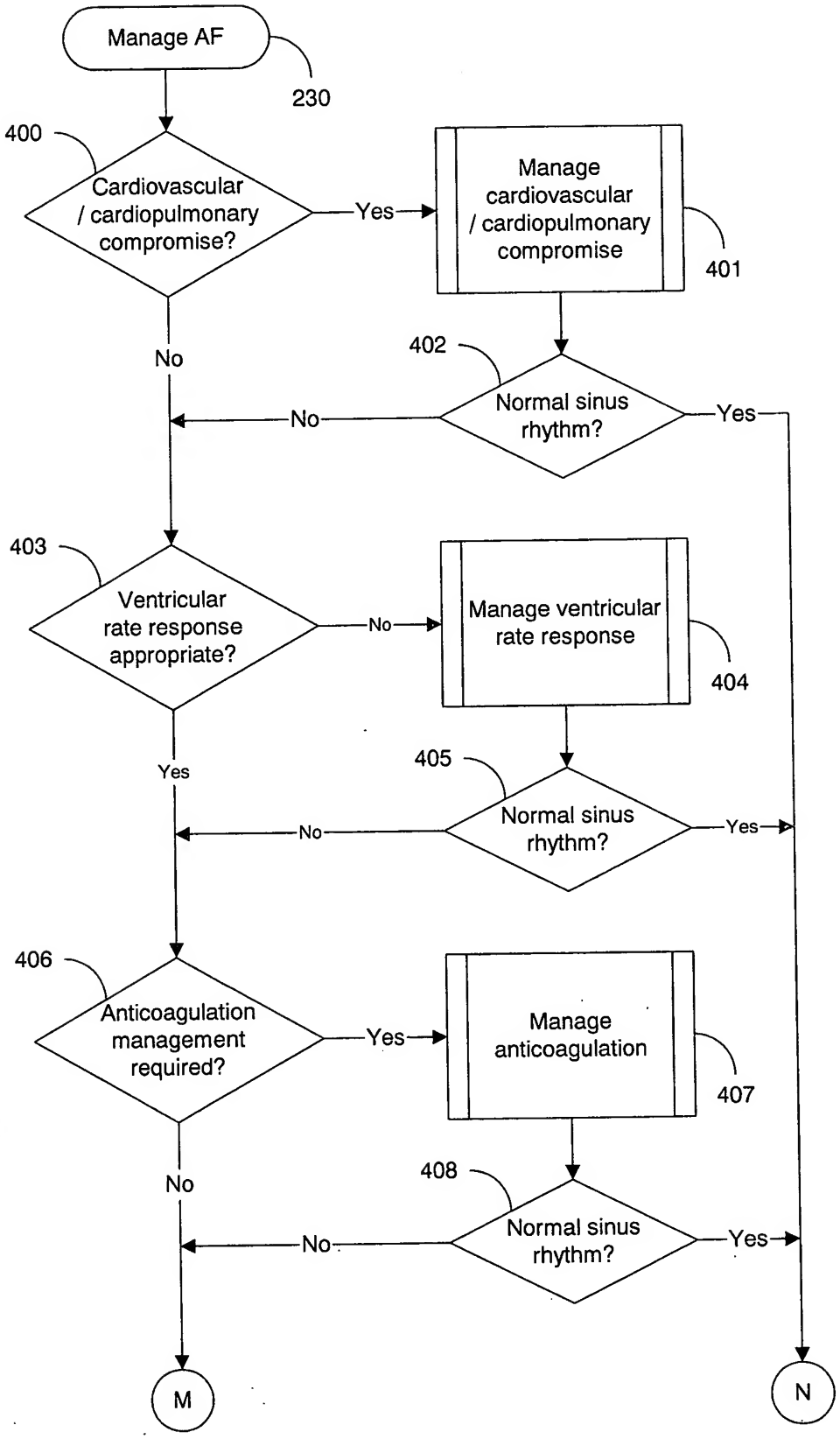

Manage AF
230
400
Cardiovascular / cardiopulmonary compromise?
Yes
Manage cardiovascular / cardiopulmonary compromise
401
No
402
Normal sinus rhythm?
No
Yes
403
Ventricular rate response appropriate?
No
Manage ventricular rate response
404
Yes
405
Normal sinus rhythm?
No
Yes
406
Anticoagulation management required?
Yes
Manage anticoagulation
407
No
408
Normal sinus rhythm?
No
Yes
M
N

Figure 17B.

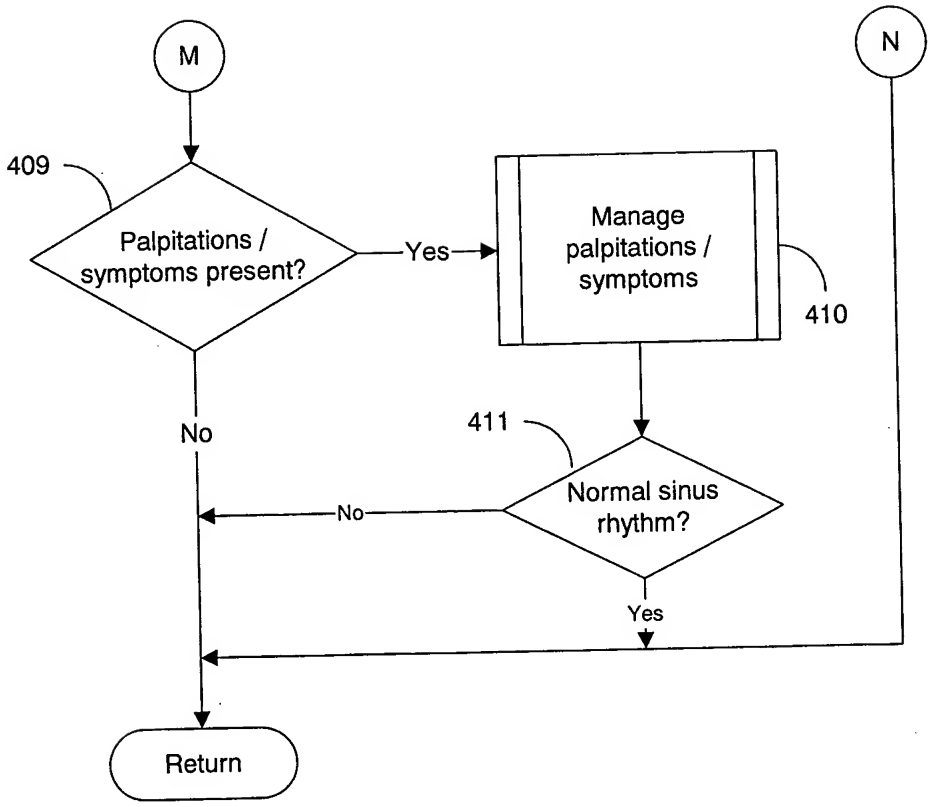
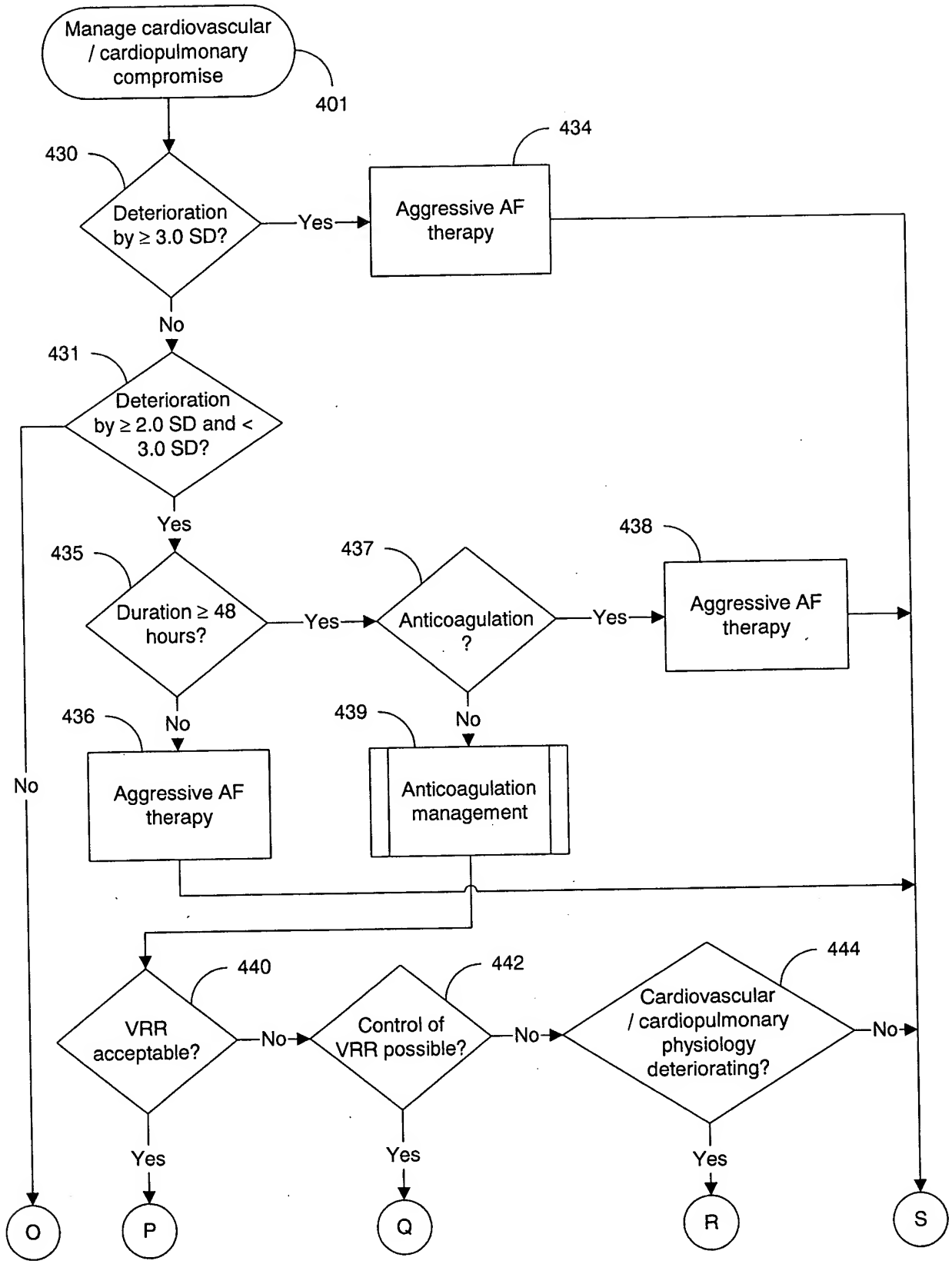

M
N
409
Palpitations / symptoms present?
Yes
Manage palpitations / symptoms
410
No
411
Normal sinus rhythm?
No
Yes
Return

Figure 18A.


Manage cardiovascular / cardiopulmonary compromise
401
430
Deterioration by ≥ 3.0 SD?
Yes
434
Aggressive AF therapy
No
431
Deterioration by ≥ 2.0 SD and < 3.0 SD?
Yes
No
435
Duration ≥ 48 hours?
Yes
437
Anticoagulation ?
Yes
438
Aggressive AF therapy
No
436
Aggressive AF therapy
No
439
Anticoagulation management
440
VRR acceptable?
No
442
Control of VRR possible?
No
444
Cardiovascular / cardiopulmonary physiology deteriorating?
No
Yes
Yes
Yes
O
P
Q
R
S

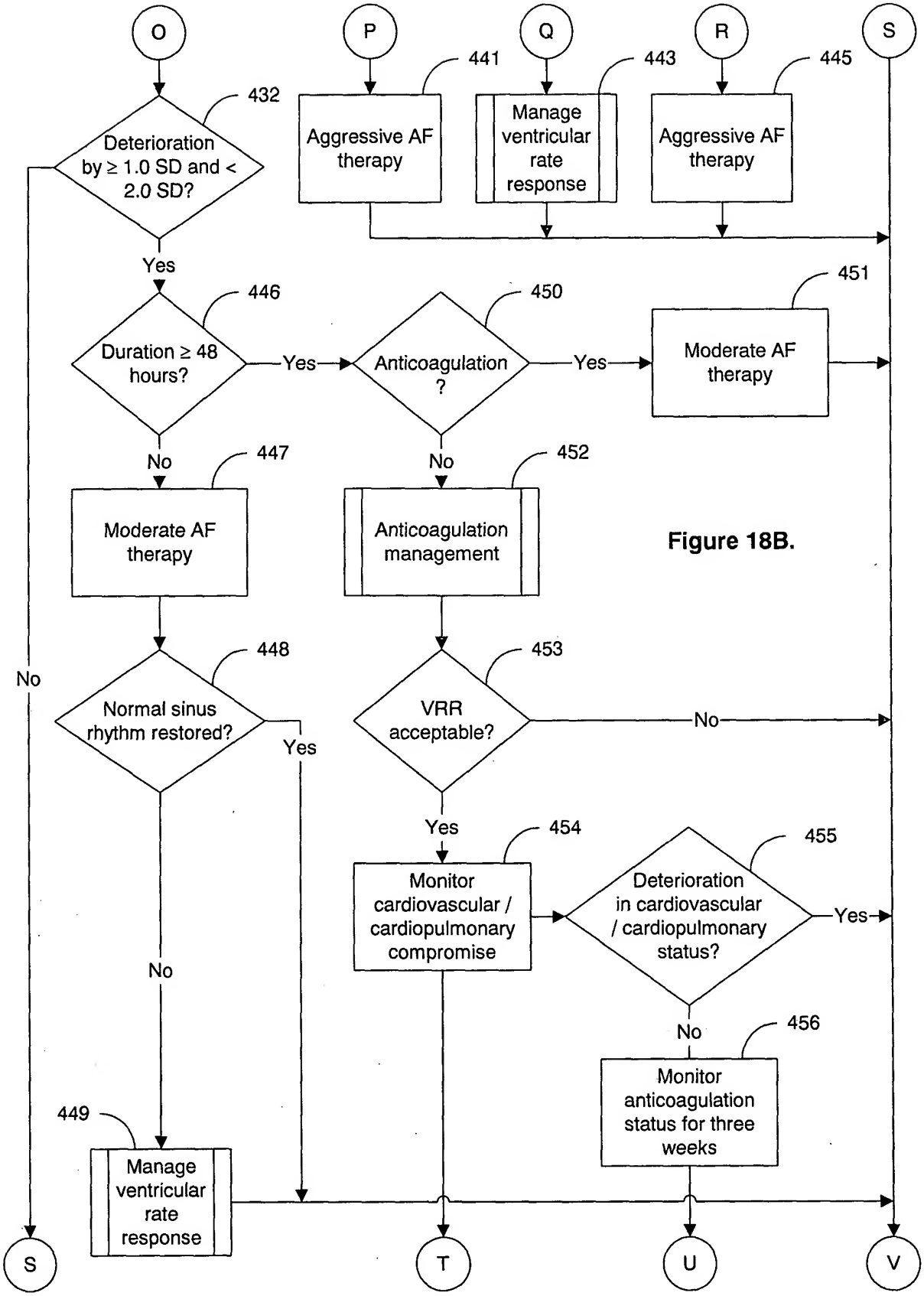

O
P
Q
R
S
432
Deterioration by ≥ 1.0 SD and < 2.0 SD?
441
Aggressive AF therapy
443
Manage ventricular rate response
445
Aggressive AF therapy
Yes
446
Duration ≥ 48 hours?
Yes
450
Anticoagulation ?
Yes
451
Moderate AF therapy
No
447
Moderate AF therapy
No
452
Anticoagulation management
No
448
Normal sinus rhythm restored?
Yes
453
VRR acceptable?
No
Yes
454
Monitor cardiovascular / cardiopulmonary compromise
455
Deterioration in cardiovascular / cardiopulmonary status?
Yes
No
456
Monitor anticoagulation status for three weeks
No
449
Manage ventricular rate response
S
T
U
V

Figure 18B.

Figure 18C.

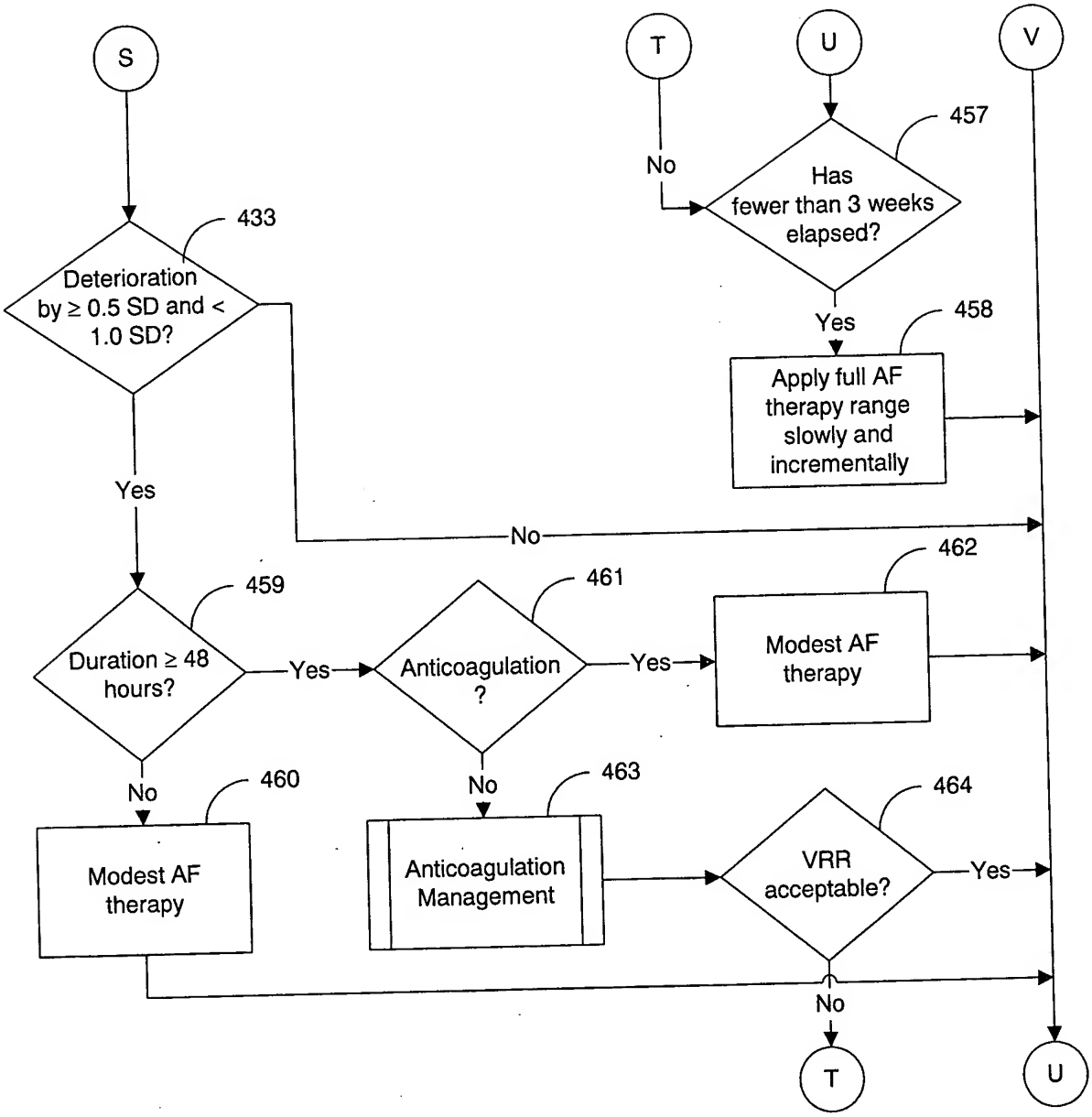

S
T
U
V
433
Deterioration by ≥ 0.5 SD and < 1.0 SD?
No
457
Has fewer than 3 weeks elapsed?
Yes
458
Apply full AF therapy range slowly and incrementally
Yes
No
459
Duration ≥ 48 hours?
Yes
461
Anticoagulation ?
Yes
462
Modest AF therapy
No
460
Modest AF therapy
No
463
Anticoagulation Management
464
VRR acceptable?
Yes
No
T
U

Figure 18D.

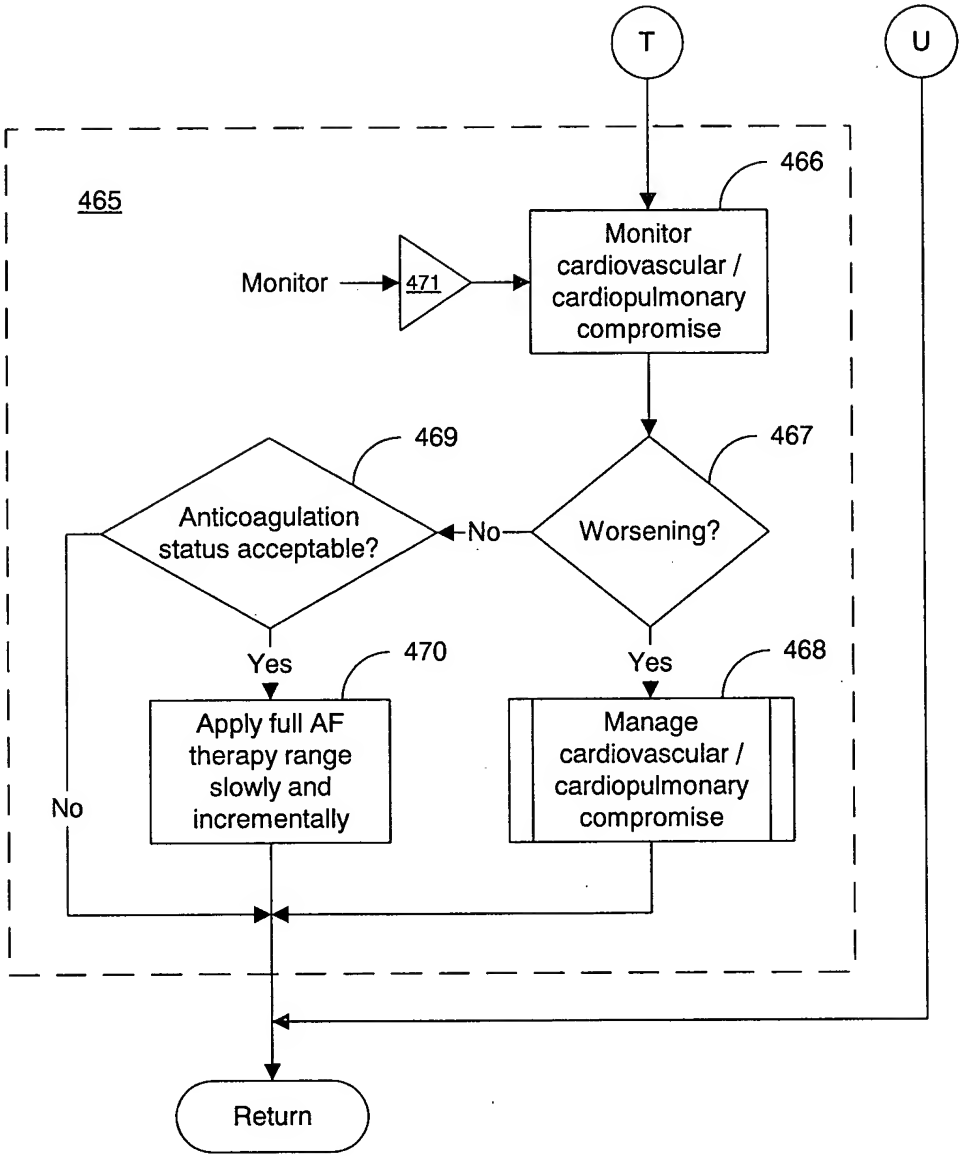

T
U
465
466
Monitor cardiovascular / cardiopulmonary compromise
Monitor
471
469
467
Anticoagulation status acceptable?
No
Worsening?
Yes
470
Yes
468
Apply full AF therapy range slowly and incrementally
Manage cardiovascular / cardiopulmonary compromise
No
Return

Figure 19.

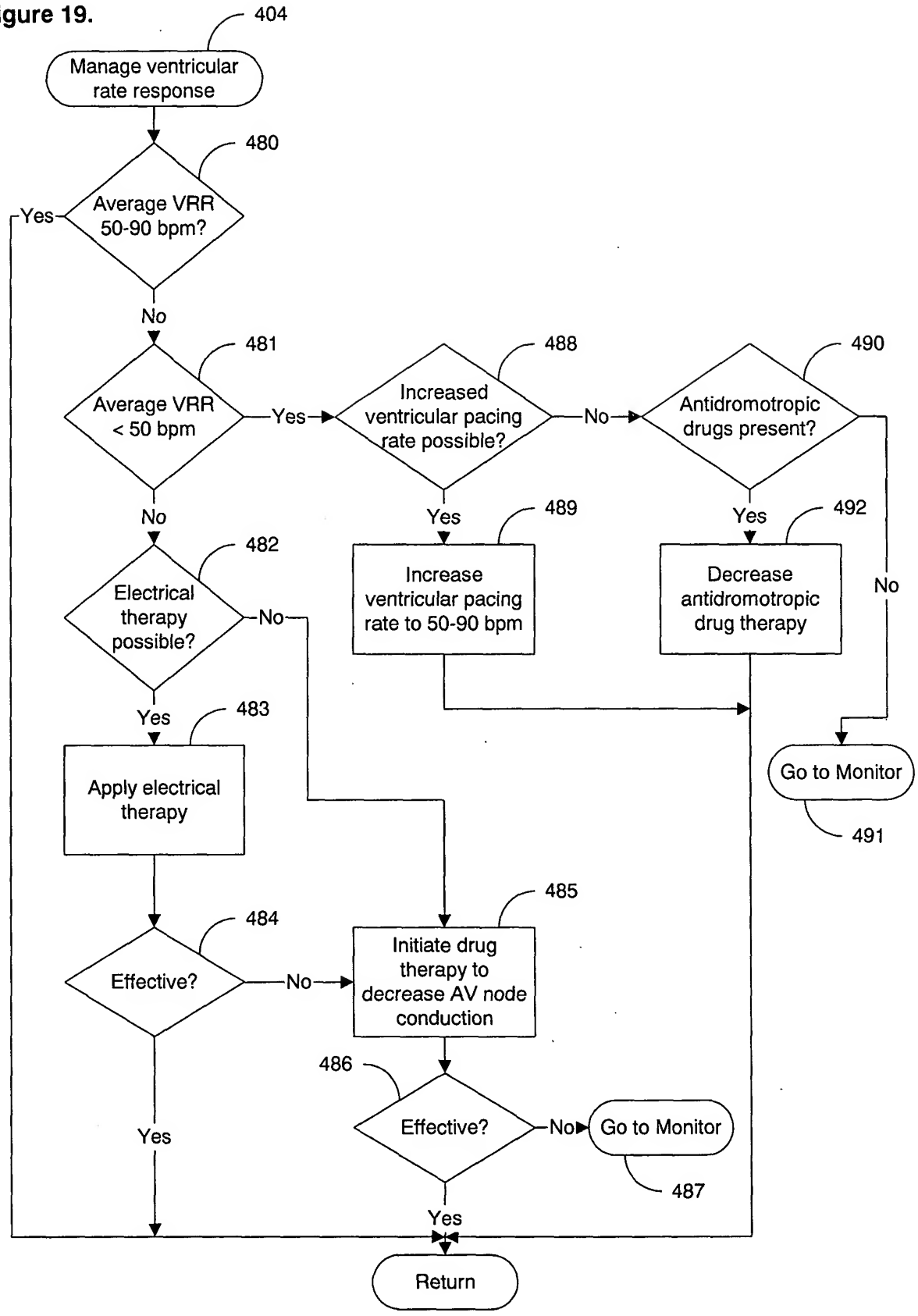

404
Manage ventricular rate response
480
Average VRR 50-90 bpm?
Yes
No
481
Average VRR < 50 bpm
Yes
488
Increased ventricular pacing rate possible?
No
490
Antidromotropic drugs present?
No
Yes
Yes
489
Increase ventricular pacing rate to 50-90 bpm
492
Decrease antidromotropic drug therapy
No
482
Electrical therapy possible?
No
Yes
483
Apply electrical therapy
Go to Monitor
491
485
Initiate drug therapy to decrease AV node conduction
484
Effective?
No
486
Effective?
No
Go to Monitor
487
Yes
Yes
Return

Figure 20.

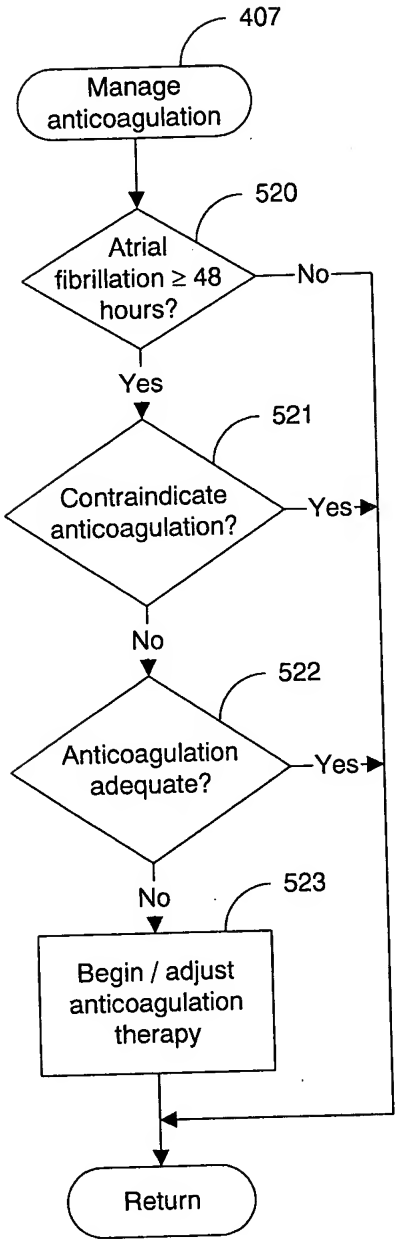
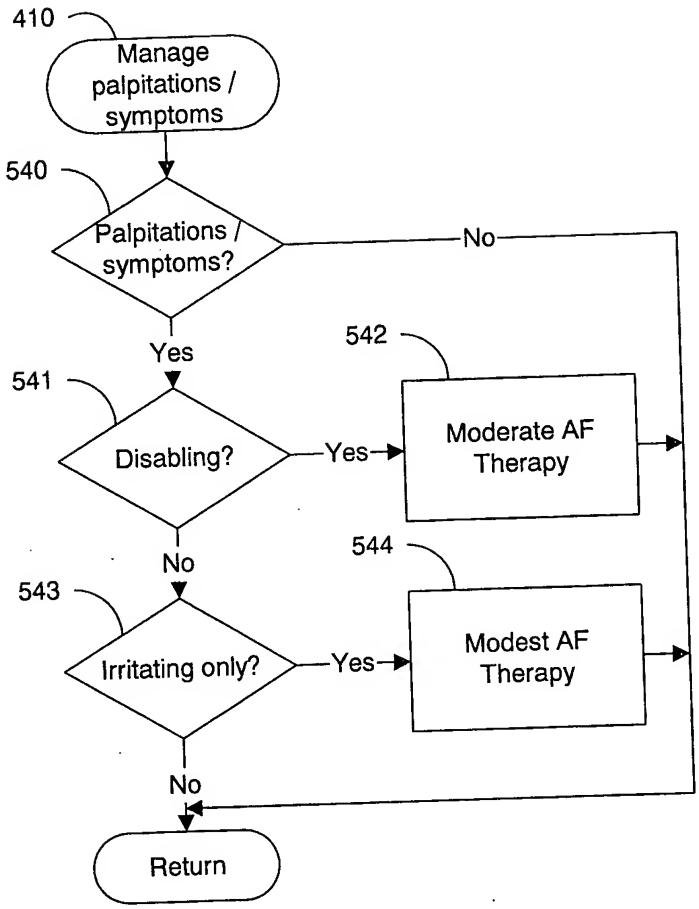

407
Manage anticoagulation
520
Atrial fibrillation ≥ 48 hours?
No
Yes
521
Contraindicate anticoagulation?
Yes
No
522
Anticoagulation adequate?
Yes
No
523
Begin / adjust anticoagulation therapy
Return

Figure 21.


410
Manage palpitations / symptoms
540
Palpitations / symptoms?
No
Yes
542
541
Disabling?
Yes
Moderate AF Therapy
No
544
543
Irritating only?
Yes
Modest AF Therapy
No
Return